ORIGINAL

To whom it may concern

Manufacturer's Authorization

Date: April 22, 2020

We Boditech Med Inc., who are official manufacturers of the ichroma and the AFIAS products, having factories at 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si Gang-won-do, Korea 200-883, do hereby declare that

ECHIPAMED PLUS SRL
str. Valea Trandafirilor 24 "B", of. 80
MD-2001, Chisinau
Republic of Moldova

is our official distributor and local representative for the ichroma and the AFIAS products of Boditech Med Inc., in the territory of the Republic of Moldova.

We declare that above mentioned company is authorized to quote, sell, subsequently negotiate and sign contracts, as well as to perform installation and after sales service of the ichroma and the AFIAS products, manufactured by us.

We hereby extend our full warranty with respect to the Goods offered by the above company.

This authorization letter will remain valid until 31.12.2020.

Boditech Med Inc.

Hye-sung Kim
Sales manger

43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gangwon-do, South Korea
Boditech Med Inc.
Euiyul Choi
PRESIDENT EUI YUL CHOI

REPUBLICA MOLDOVA mun. CHISINAU. SOCIETATEA CU RASPUNDERE LIMITATA "ECHIPAMED-PLUS" IDNO 1003600071671

Digitally signed by Iurchevici Valeriu
Date: 2020.06.22 18:27:06 EEST
Reason: MoldSign Signature
Location: Moldova

Boditech Med Inc. www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Republic of Korea
비디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373

DECLARATION OF CONFORMITY

Manufacturer:	Boditech Med Incorporated 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398 REPUBLIC OF KOREA
European Representative:	OBELIS S.A Bd. Général Wahis 53, 1030 Brussels, Belgium
Product:	AFIAS COVID-19 Ab Cat. No. : SMFP-72
Classification:	Others (Neither listed in the annex II of the IVDD, Non-self-testing device)
Conformity Assessment Route:	Self-Declaration Route According to the Annex III of the IVDD

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for In Vitro Diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

Standards applied:	EN ISO 15223-1:2016, EN ISO 13485:2016, EN 13612:2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012, EN 13975:2003, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011
Place, Date of Issue:	Chuncheon, Korea, March 24, 2020
Signature:	Dr. Eui Yul Choi / CEO

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DECLARATION OF CONFORMITY

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European Representative:	OBELIS S.A Bd. Général Wahis 53, 1030 Brussels, Belgium
Product:	AFIAS Ferritin Cat. No. : SMFP-23
Classification:	Others (Neither listed in the annex II of the IVDD, Non-self-testing device)
Conformity Assessment Route:	Self-Declaration Route According to the Annex III of the IVDD

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for In Vitro Diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards applied:	ISO 15223-1:2016, EN ISO 13485:2012, EN 13612:2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011
Place, Date of Issue:	Chuncheon, Korea, September 11, 2017
Signature:	Eyul Choi Dr. Eui Yul Choi / CEO

Boditech Med Inc. www.boditech.co.kr
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DECLARATION OF CONFORMITY

Manufacturer:	Boditech Med Incorporated 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398 REPUBLIC OF KOREA
European Representative:	OBELIS S.A Bd. Général Wahis 53, 1030 Brussels, Belgium
Product:	Boditech Ferritin Control Cat. No. : CFPO-99
Classification:	Others (Neither listed in the annex II of the IVDD, Non-self-testing device)
Conformity Assessment Route:	Self-Declaration Route According to the Annex III of the IVDD

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for In Vitro Diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

Standards applied:	EN ISO 15223-1:2016, EN ISO 13485:2016, EN 13612:2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011
Place, Date of Issue:	Chuncheon, Korea, July 17, 2019
Signature:	Eui Yul Choi

Dr. Eui Yul Choi / CEO

Boditech Med Inc. www.boditech.co.kr
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